

**Author Affiliations:** Department of Cardiovascular Surgery, Mount Sinai Medical Center, New York, New York (Chikwe, Adams); Department of Health Evidence and Policy, Icahn School of Medicine at Mount Sinai, New York, New York (Egorova).

**Corresponding Author:** Joanna Chikwe, MD, Department of Cardiovascular Surgery, Mount Sinai Medical Center, 1190 Fifth Ave, New York, NY 10029 (joanna.chikwe@mountsinai.org).

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## Sterilization of Endoscopic Instruments

**To the Editor** In their study, Dr Epstein and colleagues<sup>1</sup> found that multiresistant bacterial strains were transmitted via endoscopic instruments, even though proper cleaning and disinfecting procedures were being followed. In an accompanying Editorial, Drs Rutala and Weber<sup>2</sup> raised the question of whether such findings imply that sterilization rather than high-level disinfection should become the standard for the processing of complex, multichannel devices.

Rutala and Weber correctly pointed out that clinicians and infection-control specialists face a dilemma: flexible endoscopes are heat-sensitive and cannot be sterilized with conventional processes, such as steam sterilization. However, the only low-temperature gaseous process cleared by the US Food and Drug Administration (FDA) for many of these gastrointestinal endoscopes is ethylene oxide sterilization, which has been abandoned by many facilities because of the toxicity and carcinogenicity of ethylene oxide, the long sterilization times, and aeration efficiency.

However, another FDA-cleared alternative for low-temperature sterile processing does exist with liquid chemical sterilization. This technology has been available since the late 1980s and has never been associated with a human infection when used properly.

Soeren Mattke, MD, MPH, DSc

**Author Affiliation:** Health Advisory Services, RAND Corporation, Boston, Massachusetts.

**Corresponding Author:** Soeren Mattke, MD, MPH, DSc, Health Advisory Services, RAND Corporation, 20 Park Plaza, Ste 920, Boston, MA 02116 (mattke@rand.org).

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1. Epstein L, Hunter JC, Arwady MA, et al. New Delhi metallo- $\beta$ -lactamase-producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes. *JAMA*. 2014;312(14):1447-1455.

2. Rutala WA, Weber DJ. Gastrointestinal endoscopes: a need to shift from disinfection to sterilization? *JAMA*. 2014;312(14):1405-1406.

**In Reply** We are aware of only 1 liquid chemical sterilization process that was cleared by the FDA in 1988, the Steris System 1 sterile processing. In December 2009, the FDA ordered all health care facilities that used the System 1 processors to replace the unit with a legally marketed substitute.<sup>1</sup> In April 2010, the FDA approved the Steris System 1E Liquid Chemical Sterilant (SS1E). The SS1E uses a chemical sterilant, peracetic acid, to process devices. After treatment with peracetic acid, the device is considered to be liquid chemically sterilized. However, the SS1E then rinses the processed device with extensively treated, but not sterile, water to remove the chemical residues to ensure the processed devices are safe for the intended use.

The SS1E should be used only for processing heat-sensitive semicritical and critical devices that are compatible with the peracetic acid sterilant and processing system and cannot be sterilized by other legally marketed traditional sterilization methods validated for that device.<sup>2</sup> As a general rule, the system should not be used to reprocess critical items because critical items should be sterile when used, and, with the SS1E, the final processed device cannot be assured to be sterile after it is rinsed. To our knowledge, there have been no infections associated with the SS1E. We believe that all current endoscope reprocessing methods should be investigated to assess their capability to remove pathogens from gastrointestinal endoscopes, especially duodenoscopes due to the elevator channel.

William A. Rutala, PhD, MPH

David J. Weber, MD, MPH

**Author Affiliations:** Hospital Epidemiology, University of North Carolina Health Care, Chapel Hill.

**Corresponding Author:** William A. Rutala, PhD, MPH, Hospital Epidemiology, Occupational Health and Safety Program, Room 1001 West Wing, University of North Carolina Health Care, Chapel Hill, NC 27514 (brutala@unch.unc.edu).

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2. US Food and Drug Administration. Steris System 1E (SS1E) Liquid Chemical Sterilant—K090036. <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm207489.htm>. Accessed November 19, 2014.